REMARKS

The claims have been amended to limit them to expression of nucleotide sequences encoding therapeutic gene products. Support for this amendment is found, for example, on page 10, beginning at line 5, which begins a list of gene products that are clearly therapeutic, including both proteins and RNA molecules (lines 37, *et seq.*).

Claim 49 has also been amended to include the limitation of claim 50, requiring that the recombinant poliovirus nucleic acid be encapsidated. Claim 49 has also been amended to require that the composition be substantially free of unmodified poliovirus.

This amendment is supported, for example, on page 4 of the specification, beginning at line 7, which requires that the capsid proteins be supplied by a non-poliovirus. This avoids encapsidation of unmodified poliovirus.

Claims 55 and 56 have been amended simply to conform to the wording now present in claim 49.

No new matter has been added and entry of the amendment is respectfully requested.

The invention resides in providing reliable uncontaminated recombinant poliovirus-based vectors which are encapsidated. The Choi and Percy documents cited by the Office are distinguished in the specification itself on page 2. As noted, the work of Choi did not result in poliovirus infectious DNA that could be encapsidated, and the techniques of Percy resulted in mixtures of both modified poliovirus and wildtype. Clearly this would not be useful as any kind of a treatment vector. The present invention, on the other hand, provides poliovirus vectors that are successfully encapsidated and free of wildtype.

The Rejection Over Choi

Claims 49, 53, 55, 57, 61 and 62 were rejected as anticipated by Choi, *et al.* Claim 50 is not included in this rejection, and as the limitations of claim 50 are now included in claim 49, this rejection is obviated on this basis alone. In addition, clearly Choi does not teach the expression of a nucleotide sequence encoding a therapeutic gene product.

The Rejection Over Percy

Claims 49, 50, 53, 55, 57 and 61 were rejected as assertedly anticipated by Percy. This basis for rejection is also obviated by the limitation that the nucleotide sequence encode a therapeutic gene product. The product obtained in Percy is not a therapeutic agent gene product.

Claim 49 is further distinguished from Percy by the requirement that the composition be substantially free of unmodified poliovirus. As noted in the specification on page 2, the techniques of Percy do not result in a composition with this limitation. Accordingly, the rejection for anticipation over Percy may properly be withdrawn.

It is noted with appreciation that claims 51-52, 54, 56, 58-60 and 63 are not subject to rejection for anticipation. It is believed that claims 61 and 62 were included in error as claim 61 requires the production of an antisense sequence; therefore claim 62 is similarly not properly included in the rejection over Choi.

The Rejection Under 35 U.S.C. § 103

Claims 49-62 were rejected as assertedly obvious over Barber, *et al.*, in view of Percy and Choi, *et al.* Barber is cited as describing the use of retroviral vectors to effect the treatment of tumors and mention poliovirus as part of a laundry list of possible viral hosts that could be used. The Office takes the view that Percy and Choi teach recombinant poliovirus vectors that express

non-polio sequences when administered to a cell and provide details of polio vector construction lacking in Barber.

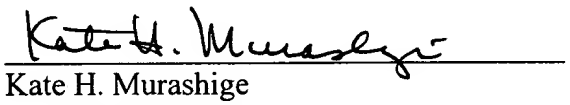
First, applicants do not believe that the inclusion of poliovirus on a list of what are, apparently, all of the retroviral possibilities that the Barber applicants could possibly think of amounts to a specific suggestion to utilize poliovirus in this context. It appears that the motivation to combine Barber with Percy or Choi is mainly motivated by the disclosure of the present invention rather than any real guidance set forth in Barber. Second, the combination does not result in the invention. As noted above, the poliovirus constructs described by Choi were incapable of being encapsidated and those prepared by Percy were contaminated with wildtype poliovirus. Neither of these compositions would meet the limitations of claim 49, the only independent claim. Even if the claimed invention were obvious to try, clearly there is no reasonable expectation of success, especially in view of the failures of Percy and Choi to prepare successful compositions although attempting to do so. Accordingly, it is believed that the currently pending claims, claims 49 and 51-63, are not suggested by the cited art.

Conclusion

The claims have been amended clearly to distinguish Percy and Choi. Further, since the teachings of Percy and Choi fail to result in compositions useful in the method of the present invention, the combination of these documents does not result in the invention. The secondary documents suggest that the invention as claimed would not be achievable. Accordingly, it is believed that the pending claims, claims 49 and 51-63 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 532572000104.

Respectfully submitted,

Dated: March 22, 2005 By: 

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